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*Attorneys for Plaintiffs  
Novo Nordisk, Inc. and Novo Nordisk A/S*

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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	:	
NOVO NORDISK INC. and	:	
NOVO NORDISK A/S	:	
	:	
Plaintiffs,	:	Civil Action No. _____
	:	
v.	:	
	:	
SANDOZ INC.	:	<i>DOCUMENT FILED ELECTRONICALLY</i>
	:	
Defendant.	:	
	:	
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**PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their attorneys, for their Complaint against Defendant Sandoz Inc. ("Sandoz"), hereby allege as follows:

### **Nature Of The Action**

1. This is a civil action for the infringement of United States Patent No. 6,677,358 pursuant to the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

### **The Parties**

2. Plaintiff Novo Nordisk Inc. is a Delaware corporation, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

3. Plaintiff Novo Nordisk A/S is a corporation organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

4. On information and belief, Defendant Sandoz is registered to do business in New Jersey, has its headquarters at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540, and has appointed Prentice Hall Corporation System, 830 Bear Tavern Road, West Trenton, New Jersey 08628 as its registered agent in New Jersey for the receipt of service of process.

### **Jurisdiction And Venue**

5. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 271(e)(2).

6. This Court has personal jurisdiction over Sandoz by virtue of, *inter alia*, Sandoz's continuous and systematic contacts with New Jersey, including having its headquarters in New Jersey, its sale of prescription drugs in New Jersey, its consent to being sued in New Jersey, as evidenced by its registration to do business in New Jersey and its appointment of a registered agent in New Jersey, and its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**Type 2 Diabetes And The '358 Patent**

8. Type 2 diabetes mellitus, also known as non-insulin dependent diabetes mellitus (“NIDDM”), is the most common form of diabetes, and affects millions of children and adults throughout the world. It is a chronic disorder characterized by hyperglycemia – elevated blood glucose levels in the body – typically as a result of insufficient insulin production in the pancreas, excessive glucose production in the liver, or a resistance to the effects of insulin at the cellular level. Hyperglycemia inhibits the normal functioning of the body’s cells, and if left uncontrolled, can severely damage the kidneys, eyes, nervous system, heart, and blood vessels. As a result, type 2 diabetes is among the leading causes of death in the United States.

9. Founded in 1923, Novo Nordisk has pioneered many key breakthroughs in diabetes treatment, and spends well in excess of \$1 billion annually on research and development in the field of diabetes care. Up until the mid-1990s, type 2 diabetic patients were generally treated with monotherapy, *i.e.*, a single oral antidiabetic drug (“OAD”). At the time, combination therapy – the treatment of diabetes with two or more OADs – was not the standard of care and was, in fact, quite rare.

10. Following a clinical trial in Australia in 1996 that produced unexpected and surprising results, Novo Nordisk pursued patent protection in 1997 relating to an important breakthrough in the treatment of type 2 diabetes: combination therapy with repaglinide and metformin.

11. On January 13, 2004, United States Patent No. 6,677,358, entitled “NIDDM Regimen,” (the “’358 patent”) was duly and legally issued by the United States Patent and Trademark Office to Novo Nordisk A/S as assignee.

12. The ’358 patent is directed to and claims a pharmaceutical composition which includes repaglinide, metformin and a carrier (claim 1) in the form of a tablet (claim 2) or a capsule (claim 3); a method for treating non-insulin dependent diabetes mellitus (“NIDDM”) by administering repaglinide and metformin to a patient in need of treatment (claim 4); and a kit that includes repaglinide and metformin (claim 5).

13. Novo Nordisk A/S has at all times been, and continues to be, the sole owner of the ’358 patent. A copy of the ’358 patent is attached hereto and incorporated herein by reference as Exhibit A.

#### **FDA-Approved Uses Of Repaglinide**

14. Novo Nordisk holds the FDA-approved New Drug Application (“NDA”) for repaglinide, and manufactures and sells repaglinide under the brand name PRANDIN<sup>®</sup>.

15. The FDA has approved repaglinide for three uses in the treatment of type 2 diabetes: (1) repaglinide by itself (i.e., monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones (“TZDs”).

16. The predominant approved use of PRANDIN<sup>®</sup> is in combination therapy with metformin.

#### **FDA Orange Book Listing For PRANDIN<sup>®</sup>**

17. After an NDA is approved by the FDA, the NDA holder must submit FDA Form 3542 (“Patent Information Submitted Upon and After Approval of an NDA or Supplement”).

18. On Form 3542, the FDA requests that an NDA holder propose a “use code” narrative for an approved drug based on a description of either the “approved indication” or “method of use.”

19. The FDA publishes use codes and information about patent protection for each approved drug in a book called “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as the “Orange Book”).

20. The Orange Book listing for PRANDIN<sup>®</sup> includes the ’358 patent.

21. When the ’358 patent was issued in 2004, the “Indications and Usage” section of the FDA-approved label for PRANDIN<sup>®</sup> contained a separate indication for FDA-approved uses of repaglinide in combination therapy: “PRANDIN is also indicated for combination therapy use (with metformin or thiazolidinediones) to lower blood glucose in patients whose hyperglycemia could not be controlled by diet and exercise, plus monotherapy with metformin, sulfonylureas, repaglinide, or thiazolidinediones.”

22. Consistent with the FDA-approved label for PRANDIN<sup>®</sup> in 2004, Novo submitted on Form 3542 the following proposed use code description for PRANDIN<sup>®</sup>: “Use of repaglinide in combination with metformin to lower blood glucose.”

23. The FDA assigned use code U-546 to the proposed use code description for PRANDIN<sup>®</sup> and published the U-546 use code and description in the Orange Book.

24. In November 2007, the FDA concluded that separate indications of usage for PRANDIN<sup>®</sup> should be eliminated and directed Novo Nordisk to revise its labeling with a single approved indication:

“Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.”

25. Novo Nordisk submitted a proposed new label in January 2008 with the new approved indication noted in paragraph 24 above, and the FDA approved the new PRANDIN<sup>®</sup> label in July 2008.

26. In May 2009, Novo Nordisk submitted to the FDA a proposed amended use code description for PRANDIN<sup>®</sup> to track the new approved indication for PRANDIN<sup>®</sup> in the revised labeling for PRANDIN<sup>®</sup>.

27. The FDA assigned use code U-968 to the proposed amended use code description for PRANDIN<sup>®</sup> and published the U-968 use code and description in the Orange Book. The U-968 use code accurately describes the approved indication for PRANDIN<sup>®</sup>.

**The Federal Circuit Decision Relating To The Use Code For PRANDIN<sup>®</sup>**

28. In a decision dated April 14, 2010, the United States Court of Appeals for the Federal Circuit addressed a dispute over the amended use code description for PRANDIN<sup>®</sup>. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010).

29. In *Novo Nordisk A/S, et al. v. Caraco Pharm. Labs., Ltd., et al.*, Civil Action No. 2:05 CV 40188 (E.D. Mich.) (“*Caraco*”), the district court had ordered Novo Nordisk to request that the FDA restore the original use code for PRANDIN<sup>®</sup>.

30. The Federal Circuit vacated the district court injunction. Writing for the majority, Chief Judge Randall R. Rader held that, *inter alia*, the terms of the Hatch-Waxman Act do not authorize an order compelling the patent holder to change its use code narrative. In his concurring opinion, Judge Raymond C. Clevenger stated that “Novo did nothing that was illegal or forbidden” and that “there is nothing illegal, or even incorrect, about Novo’s current use code.” *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010).

31. On July 29, 2010, the Federal Circuit denied Caraco's petition for a rehearing by the panel that vacated the district court injunction or rehearing *en banc*. See *Novo Nordisk A/S & Novo Nordisk v. Caraco Pharm. Labs., Ltd.*, 615 F.3d 1374 (Fed. Cir. 2010).

### **The Caraco Judgment**

32. Following the Federal Circuit's decisions relating to the use code for PRANDIN<sup>®</sup>, proceedings on the remaining issues in the *Caraco* action resumed in the district court. Among other things, Novo Nordisk renewed a motion to dismiss the lawsuit for lack of subject matter jurisdiction, arguing that Caraco's actions before the FDA had defeated the jurisdictional basis for suit. The district court in *Caraco* denied that motion. See *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 2010 WL 3942727, at \*4 (E.D. Mich. Oct. 6, 2010).

33. On January 19, 2011, after a bench trial, the district court found Claim 4 of '358 patent invalid for obviousness and unenforceable for inequitable conduct. See *Nordisk A/S, et al. v. Caraco Pharm. Labs., Ltd.*, 2011 WL 163996 (E.D. Mich. Jan. 19, 2011).

### **Supreme Court And Federal Circuit Proceedings In Caraco Case**

34. Caraco has appealed the Federal Circuit's decision relating to the use code for PRANDIN<sup>®</sup> to the Supreme Court. Novo Nordisk is opposing Caraco's appeal to the Supreme Court on multiple grounds, including the district court's lack of subject matter jurisdiction.

35. Novo Nordisk has appealed the January 19, 2011 judgment by the district court in the *Caraco* case to the Federal Circuit. Novo Nordisk's appeal from the January 19, 2011 judgment has been stayed pending the Supreme Court's decision on Caraco's appeal of the Federal Circuit's decision relating to the use code for PRANDIN<sup>®</sup>. See *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, No. 2011-1223 (Fed. Cir. July 27, 2011).

**Sandoz's Intent To Induce, Promote And  
Encourage Infringement Of The '358 Patent**

36. On information and belief, prior to the January 19, 2011 judgment in the *Caraco* case, Sandoz submitted Abbreviated New Drug Application (“ANDA”) No. 078555 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic 0.5, 1, and 2 mg oral repaglinide tablets prior to the expiration of the '358 patent.

37. On information and belief, ANDA No. 078555 refers to and relies upon Novo Nordisk's NDA for PRANDIN<sup>®</sup> and purports to contain data showing bioequivalence of Sandoz's repaglinide with PRANDIN<sup>®</sup>.

38. In a letter to Novo Nordisk dated September 2, 2011 (the “ Notification Letter”), Sandoz stated that ANDA No. 078555 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as a “Paragraph IV certification”) alleging that the '358 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sandoz's repaglinide. The letter further alleges that Novo Nordisk has used the '358 patent to monopolize repaglinide by improperly amending the use code description for PRANDIN<sup>®</sup>.

39. On information and belief, Sandoz's proposed label for its generic repaglinide will not restrict the use of repaglinide to monotherapy, or to combination therapy with compounds other than metformin. On information and belief, Sandoz's proposed label for generic repaglinide will not instruct physicians not to use repaglinide in combination with metformin.

40. Based on discussions with the FDA, Novo Nordisk understands that the FDA will not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin. In the event the FDA approves



Sandoz's ANDA, it will necessarily include labeling which recites instructions for the use of repaglinide in combination with metformin.

41. On information and belief, Sandoz knows that the predominant use of repaglinide today is in combination with metformin for the treatment of type 2 diabetes mellitus. On information and belief, Sandoz further knows that it stands to significant profits by supporting, promoting and encouraging the infringement of the '358 patent.

42. On information and belief, Sandoz filed and is pursuing its ANDA for generic repaglinide with the knowledge and intent that its product, if approved, would predominantly be used in combination with metformin for the treatment of type 2 diabetes mellitus.

43. On information and belief, Sandoz intends to and will support, promote and encourage the use of its generic repaglinide in combination with metformin for the treatment of type 2 diabetes mellitus.

44. On information and belief, Sandoz intends to and will support, promote and encourage the manufacture, use and sale of its generic repaglinide alongside metformin for the treatment of type 2 diabetes mellitus.

45. On information and belief, Sandoz does not intend to take any actions to discourage the use of its generic repaglinide in combination with metformin for the treatment of type 2 diabetes mellitus.

**Count 1: Infringement of U.S. Patent No. 6,677,358**

46. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-45 of this Complaint.

47. Sandoz's submission of ANDA No. 078555 to the FDA with a Paragraph IV certification regarding the '358 patent, with the purpose of obtaining approval to engage in the

commercial manufacture, use, or sale of repaglinide before the expiration of the '358 patent, constitutes infringement of the '358 patent under 35 U.S.C. § 271(e)(2)(A).

48. On information and belief, upon approval of ANDA No. 078555, Sandoz will directly and/or indirectly infringe the '358 patent under 35 U.S.C. § 271(a), (b), and (c).

49. The acts of infringement set forth above will cause Novo Nordisk irreparable harm for which it has no adequate remedy at law, and will continue unless the FDA's approval of ANDA No. 078555 is stayed until the expiration of the '358 patent, and unless Sandoz is preliminarily and permanently enjoined by this Court.

**WHEREFORE**, Novo Nordisk prays that this Court:

a. Enter a judgment that Sandoz has infringed the '358 patent under 35 U.S.C. § 271(e)(2)(A);

b. Stay FDA approval of Sandoz's ANDA for at least thirty months, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii);

c. Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sandoz's generic repaglinide shall be a date not earlier than the date of the expiration of the '358 patent, including any extensions;

d. Enter a judgment that Sandoz's manufacture, use, offer for sale, or sale in the United States or importation into the United States of the repaglinide products that are the subject of ANDA No. 078555 will infringe and actively induce the infringement of the '358 patent under 35 U.S.C. § 271(a);

e. Enter a judgment that Sandoz's activities have made this an exceptional case under 35 U.S.C. § 285;

f. Preliminarily and permanently enjoin and restrain Sandoz and its respective officers, directors, agents, servants, employees, and attorneys, and those in active concert or participation with them, from the manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the repaglinide products that are the subject of ANDA No. 078555 and any other product that infringes or induces infringement of the '358 patent, prior to the expiration of the '358 patent, including any extensions;

g. Grant Novo Nordisk compensatory damages in an amount to be determined at trial including both prejudgment and postjudgment interest if Sandoz commercially manufactures, uses, offers for sale, or sells in the United States, or imports into the United States, the repaglinide products that are the subject of ANDA No. 078555, or any other product that infringes or induces infringement of the '358 patent, prior to the expiration of the '358 patent, including any extensions;

h. Award Novo Nordisk enhanced damages;

i. Award Novo Nordisk its costs, expenses, and attorney fees that it incurs in prosecuting this action; and

j. Grant Novo Nordisk any such other and further relief as the Court may deem just and proper.

Dated: October 14, 2011  
Newark, New Jersey

Respectfully submitted,

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